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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/674,815	12/07/00	ADMATSU	A 5836-01-MJA

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EXAMINER

KWON, B

ART UNIT	PAPER NUMBER
1614	8

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/674,815

Applicant(s)

AOMATSU, AKIRA

Examiner

Brian-Yong S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 1-9, drawn to a stabilized pharmaceutical preparation containing a 4-amino-3-substituted-butanoic acid derivative.

Group II, claim(s) 10-17, drawn to a process of making a stabilized pharmaceutical preparation containing a 4-amino-3-substituted-butanoic acid derivative.

The inventions listed as Group I-II do not relate to a single inventive concept under PCT Rule 13.1. Because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature linking groups I-II appears to be that they all relate to "4-amino-3-substituted-butanoic acid derivatives". However, The claimed "4-amino-3-substituted-butanoic acid derivatives", namely gabapentin, pregabalin or baclofen, are well known compounds in the art (see WO 9819674; US 6127418; US 4894476; US 5025035; US 4126684; US 3471548; and US 3634428). Therefore, the technical feature linking the inventions of groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

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Accordingly, Groups I-II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Therefore, there is not unity of invention.

2. Additionally, this application contains claims directed to more than one species of the generic invention. Claim 1 is generic to a plurality of disclosed species comprising general formula. Since the above groups themselves are inclusive of compounds which lack unity, applicant is required to elect a single disclosed species, from under the instant claims of the elected Group, to which the claims shall be restricted if no generic claim is finally held to be allowable. Moreover, whatever specific compound is ultimately elected, a generic concept will be identified by the examiner as the inventive group for examination. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. During a telephone conversation with Mr. David R. Kurlandsky on August 23, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9 and gabapentin as the elected species. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Claim Objections

4. Claims 4-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Claims 4-9 are objected to because of the following informalities: Misspelling of word such as "4-amino-3-substituted-butanic acid". Appropriate correction is required.

Specification

The abstract of the disclosure is objected to because typographical error "(3)" in page 45, Table 4, is present. The reference to (3) is wrong. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Applicant recites a 4-amino-3-substituted-butanoic acid derivative having the general formula in Claim 1, wherein R1 and R2 are defined with various groups. However, the drawing of general formula in claim 1 does not contain any R groups, which make claims 1-9 vague and indefinite. Does applicant mean to incorporate the structure in page 6, line 17 of the instant specification into Claim 1? Applicant is requested to clarify.

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6. The instant specification discloses that the present invention is directed to a stabilized 4-amino-3-substituted-butanoic acid derivative, namely gabapentin, by adding amino acid as an effective stabilizer. However, it is unclear in Claim 1 that whether the alpha-amino acid is part of the substituent of R2 or independently used as the stabilizer. Applicant is requested to clarify.

7. In the description and in the claims the term "4-amino-3-substituted-butanoic derivative" is used both for the 4-amino-3-substituted-butanoic derivative alone (the substance according to the mentioned formula) as well as for the combination of this substance with the stabilizing amino acid. Hence, the required clarity is missing. Applicant is requested to clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodruff (US 5084479).

Woodruff teaches a composition comprising gabapentin and glycine (see column 7, line 11-12 and Table 3).

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodruff (US 5084479).

The Robson et al teaches a composition comprising baclofen and glycine in the form of tablet (see Example 2).

It is noted to applicant that recitation of inherent property such as the use of glycine as a stabilizer is not limited to the interpretation of composition claim.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

**ZOHREN FAY
PRIMARY EXAMINER
GROUP 1600**

